



www.bioinformation.net
Volume 22(9)



Research Article

Received September 1, 2026; Revised September 30, 2026; Accepted September 30, 2026, Published September 30, 2026

DOI: 10.6026/973206300225985

SJIF 2026 (Scientific Journal Impact Factor for 2026) = 8.478

2022 Impact Factor (2023 Clarivate Inc. release) is 1.9

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Edited by P Kanguane

Citation: Das *et al.* Bioinformation 22(9): 5985-5990 (2026)

Patterns of psychiatric adverse drug reactions at an Eastern Indian tertiary care hospital

Krishnasish Das^{1†}, Prasanjit Das^{2†}, Bisweswar Ojha³, Alapan Das², Tirthankar Deb^{*,1}, Soumitra Mandal¹ & Sukriti Mukherjee⁴

¹Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Kalyani, West Bengal, India; ²Department of Pharmacology, Krishnanagar Institute of Medical Sciences, Krishnanagar, West Bengal, India; ³Department of Pharmacology, Manipal Tata Medical College, Jamshedpur, Jharkhand, India; ⁴Department of Psychiatry, Mandakini Institute of Medical Sciences and Hospital, Aistala, Ranaghat, West Bengal, India; *Corresponding author †Equally Contributed

Affiliation URL:

<https://www.aiimskalyani.edu.in/>

<https://kimsmh.in/>

<https://www.manipal.edu/mtmc>

<https://www.mandakinimedicalcollege.in/>

Author contact:

Krishnasish Das - E-mail: kdasexams@gmail.com; Phone: +91 7980781112

Prasanjit Das - E-mail: docprasanjitdas@gmail.com; Phone: +91 9074384749

Bisweswar Ojha - E-mail: bisweswar.ojha@manipal.edu; Phone: +91 8584065855

Alapan Das - E-mail: newborn91@gmail.com; Phone: +91 7001737617

Tirthankar Deb - E-mail: tirthankar.pharma@aiimskalyani.edu.in; Phone: +91 9088859953

Soumitra Mandal - E-mail: soumitra.pharma@aiimskalyani.edu.in; Phone: +91 7055241906

Sukriti Mukherjee - E-mail: mukherjeesukriti@gmail.com; Phone: +91 8240249265

Abstract:

Adverse drug reactions (ADRs) are an important cause of treatment-related morbidity in psychiatric practice, yet data describing their clinical profile from Eastern India remain limited. Among 150 reported ADRs, females accounted for 69.3% of cases, central nervous system reactions were the most frequent (52%), followed by metabolic/endocrine (16.7%) and gastrointestinal (13.3%) reactions, while sedation (18%), weight gain (13.3%) and drowsiness (12%) were the commonest adverse events, with escitalopram, lithium and olanzapine being the most frequently implicated drugs. Most ADRs were classified as probable (63.3%), mild (96.7%) and probably preventable (60%), whereas serious ADRs were uncommon (2%). Thus, data shows that psychiatric ADRs in routine clinical practice are largely mild and preventable, supporting the need for strengthened pharmacovigilance, early detection and systematic monitoring to improve the safety of psychopharmacotherapy.

Keywords: Adverse drug reactions (ADRs), pharmacovigilance, psychiatry, psychotropic drugs and spontaneous reporting

Background:

Psychiatric disorders are one of the main causes of global health issues. According to World Health Organization (WHO), in 2019, 1 in every 8 people, or 970 million people all over the world was having a mental disorder [1]. Most common psychiatric disorders for which lifelong therapy is required are schizophrenia, bipolar disorder, obsessive-compulsive disorder, generalized anxiety disorder and post-traumatic stress disorder [2]. Globally, Adverse Drug Reactions (ADRs) result in around 0.3% to 6.7% of hospital deaths, thereby making them a major cause of mortality [3]. The phenomenon of ADRs in the Psychiatric setting can arise because of polypharmacy, drug-drug interactions and a wide range of variable individual responses [4]. Despite the greater proportion of ADRs in psychiatric settings, it is widely accepted that underreporting is still a major problem in Indian Scenario with reporting less than 1%, ultimately hindering drug safety efforts [5]. Studies have shown that metabolic, neurological and cardiovascular ADRs are the most commonly described ADR within psychiatric practice, with medications such as antidepressants and antipsychotics being the most common ones [6]. Knowledge of ADR patterns and associated factors are always necessary for choosing the right guideline based pharmacotherapy and decreasing the medication-related risks [7]. Therefore, it is of interest to investigate the ADR patterns in patients visiting psychiatric setting at a tertiary care hospital, thereby analyzing their seriousness, severity, causality and preventability for enhancing patient safety.

Materials and Methods:

This study was conducted by the Department of Pharmacology in liaison with the ADR monitoring centre (AMC)-Nadia at AIIMS Kalyani, collaborating with the Department of Psychiatry.

ADR were identified primarily through spontaneous reporting during routine clinical care. Reports were initiated either by patients during outpatient or inpatient encounters or by treating psychiatrists based on history and clinical observation. During follow-up visits, clinicians routinely enquired about commonly encountered adverse effects as part of usual care; however, no structured checklist, trigger tool, or active surveillance method was employed. Suspected ADRs were documented using the standard Pharmacovigilance Programme of India (PvPI) ADR reporting form (v1.4) and forwarded to the AMC-Nadia directed by Department of Pharmacology. Each report was screened for completeness by the residents appointed at AMC-Nadia and additional clinical details were sought from medical records or treating clinicians when feasible. The data was collected following approval from the Institutional Ethics Committee of AIIMS Kalyani from a local database preserved at AMC-Nadia in the Department of Pharmacology for the duration of 19 months, from January 2023 to July 2024. The primary objective was to examine the patterns of reported ADRs, identifying the most commonly contributing drugs used to treat psychiatric ailments. Key secondary objectives include analyzing the causality, severity and preventability of ADRs in patients attending both outpatient and inpatient departments of psychiatry in the hospital. Causality between the suspected drug and the ADR was too evaluated using the WHO-UMC causality assessment system. Severity and preventability of the ADRs were also assessed using the Hartwig's severity assessment scale and the modified Schumock and Thornton scale respectively. Descriptive statistics has been used as proportion and percentages.

Results:

Among 150 patients complaining ADRs, 104 (69.3%) were

females. The median age of the patients was 30 years. A total number of 150 ADRs were reported. Among them, maximum number of cases were reported in August 2023 (30), followed by July 2023 (26) and September 2023 (20). In 2024, there was a decreasing trend, with the least number of ADRs being reported in June 2024 (1) (**Figure 1**). Most of the reports (78, 52%) were related to the central nervous system followed by (25, 16.7%) ADRs related to the metabolic and endocrine system, (20, 13.3%) ADRs associated to the gastrointestinal system and (10, 6.7%) ADRs were dermatological reactions. A very few numbers of ADRs connected to cardiovascular, hepatobiliary, hematological and reproductive systems were reported (**Figure 2**). Most frequent reported ADR was Sedation (27, 18%) followed by weight gain (20, 13.3%), drowsiness (18, 12%) and dizziness (15, 10%) (**Table 2**). Extrapyramidal symptoms, tremors, gastritis, constipation, nausea and vomiting and skin rashes were also reported. Potentially clinically significant ADRs like QTc prolongation, hyponatremia, agranulocytosis, hepatotoxicity and hyperprolactinemia were also informed. The most common drug associated with ADRs in this study was Escitalopram, accounting for 18 (12%) reported ADRs. This was followed by lithium with 17(11.3%) ADRs, Olanzapine with 16 (10.7%) ADRs, Valproate with 15 (10%) ADRs and risperidone with 14 (9.3%) ADRs. Drugs like clozapine, fluoxetine, amitriptyline, lamotrigine and haloperidol also contributed to the ADR burden (**Figure 3**). The estimated median time of occurrence of the ADRs after administration of the drug came out to be 10 days (IQR: 5, 21). In 70 (46.66%) of the cases, the offending drug was withdrawn. Dose was reduced in 36 (24%) of the cases and for 24 (16%) of the cases, the dose of the suspected drug was not changed. However, dose escalation was also required in 6 (4%)

cases. Drug rechallenge was not done in any of the cases. In 34 (22.7%) of the cases, patient was completely recovered, while in case of 19 (12.7%) ADRs, the patients were recovering at the time of reporting. Whereas the patients did not recover in 7 (4.66%) of the cases. But the outcome was unknown in 90 (60%) of the cases (**Figure 1**). A total of 95 (63.3%) of ADRs were classified as probable and 55 (36.7%) were possible as per the WHO-UMC causality assessment scale. Regarding the severity assessment, 145 (96.7%) cases were determined as mild, while 5 (3.3%) cases were classified as moderate as per the modified Hartwig’s severity assessment scale. No severe ADR has been reported. Based on the preventability assessment by Modified Schumock and Thornton scale, 90 (60%) ADRs were found to be probably preventable followed by 45 (30%) ADRs as not preventable and 15 (10%) ADRs as definitely preventable (**Table 1**). Only 3 (2%) of the reported ADR cases were serious, as per the WHO-UMC criteria. In the first case, the patient developed deranged liver enzymes suspected to be caused by sodium valproate, resulting in a prolonged hospital stay. After discontinuing valproate and monitoring, liver enzymes gradually normalized within 10 days. In the next case, the patient developed QTc prolongation after addition of fluconazole with clozapine. This is an example of pharmacokinetic drug-drug interaction. Withdrawn of fluconazole, a Cytochrome P450 inhibitor normalized the QTc within 4 days. In the last case, patient developed rashes over the palms and soles that later became generalized, requiring hospitalization after 10 days of chlorpromazine administration. Following withdrawal of the drug, the rashes gradually resolved within a week, with near-complete recovery after one month.

Table 1: Various assessment scales for ADRs

Scales	Outcomes (N=150)			Total
	Certain	Probable	Possible	
WHO-UMC causality assessment	0	95	55	150
Modified Hartwig’s severity	Mild	Moderate	Severe	
	145	5	0	
Modified Schumock and Thornton preventability	Definitely preventable	Probably preventable	Not preventable	
	15	90	45	

Table 2: Five most common ADRs reported

Adverse Drug Reaction	N (%)
Sedation	27 (18)
Weight gain	20 (13.3)
Drowsiness	18 (12)
Dizziness	15 (10)
Extrapyramidal symptoms	6 (4)

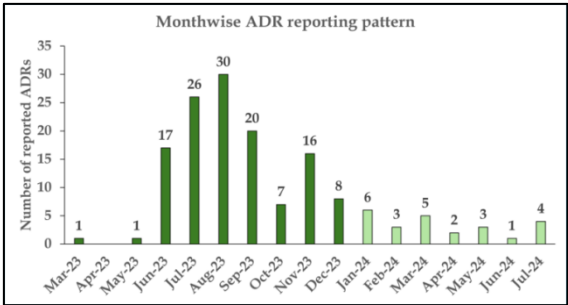
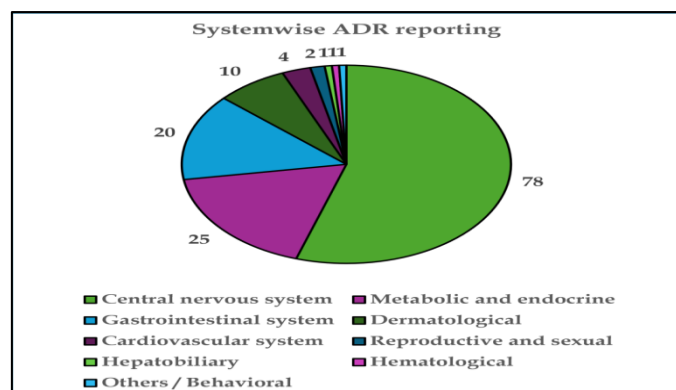
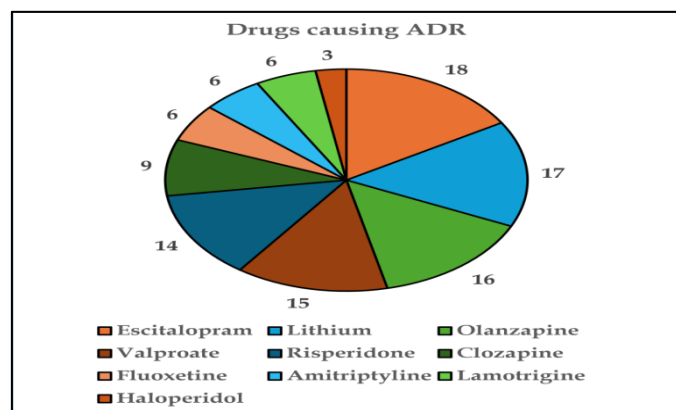


Figure 1: Pattern of monthly reporting of ADRs**Figure 2:** Schematic pie chart of system wise ADR reporting**Figure 3:** Schematic pie chart of drugs causing ADRs

Discussion:

This record based retrospective observational study was conducted with the objectives to provide light on the pattern of adverse drug reactions (ADRs) that are being reported in the psychiatric clinical practice at a tertiary care hospital over 19 months. Among the 150 patients who experienced ADRs, median age was around to be 30 years with a female predominance (69.3%) [8]. As this study was based on spontaneously reported ADRs from a pharmacovigilance database, the total number of exposed patients, prescriptions and OPD/IPD attendees during the study period was not available. Therefore, incidence rates and comparative risks could not be calculated. The findings represent the distribution of reported ADRs and should not be interpreted as reflecting true drug-specific risk. Female predominance in reporting is also supported by the existing literature [9, 10, 22]. In our study, possible explanations of the findings can be attributed to pharmacokinetic and pharmacodynamic variations between genders in physiology and possible differences in reporting of adverse reactions and health seeking behaviors [11, 12]. However, due to scarcity of gender specific prescription data or exposure statistics, any gender based interpretation should not be as inferential or as evidence of biological susceptibility [13]. But, as

there is no sex-specific exposure data in this study, we cannot conclude that women are at increased risk. This finding actually shows the percentage of reported ADRs within this confined study setting. Among the reported ADRs, events involving Central nervous system were the commonest (52%), followed by metabolic and endocrine ADRs (16.7%) and gastrointestinal reactions (13.3%). Sedation (18%), weight gain (13.3%), drowsiness (12%) and dizziness (10%) were the common reactions. This is in line with a recently published similar record based study of Eastern India, where neurological system involvement was prominent and among all the departments, psychiatry contributed to the largest proportion of reports [22]. This pattern also matches with the well-established pharmacological profiles of drugs commonly used in psychiatric disorders and also supported by several similar studies [14]. Whereas, broader studies from Eastern Odisha and Kerala reported dermatological reactions most commonly [23, 24]. Actually, ADR profiles may differ based on the reporting departments, usage of usage of drugs. Due to the predominance of sedative and metabolic adverse effects is clinically relevant, as these reactions may influence treatment adherence and long-term cardiometabolic risk. The relative percentages of the different types of ADRs like sedation, weight gain and drowsiness, in the present analysis are within the range reported by the various studies in the Indian settings [15, 16] proving that the overall pattern of ADR reporting is approximately same in the tertiary care psychiatric population in India. Drugs like olanzapine, risperidone, clozapine and amitriptyline are having strong antihistaminergic and serotonergic effects and also these are frequently associated with sedative and metabolic effects [5]. The phenomenon of weight gain too highlights the difficulties of managing metabolic ADRs [17] in psychiatric care, which may have implications for long-term physical health and medication adherence. A good proportion of patients developed extrapyramidal symptoms (4%) and gastrointestinal disturbances like nausea and vomiting (4%) and gastritis (3.3%). These are frequently linked to dopamine antagonism and serotonergic activity of antipsychotics and SSRIs, respectively. Dermatological ADRs such as rash and hair fall were also reported, mainly related to lamotrigine and valproate and known for their potential for causing hypersensitivity reactions [18]. Escitalopram was the most frequently implicated drug among spontaneously reported ADRs during the study period, followed by lithium, olanzapine, valproate and risperidone. Similar finding has been observed in the study conducted by Das *et al.* [22]. In the study conducted by Sankhi *et al.*, regarding ADRs due to antidepressant drugs in psychiatric patients, selective serotonin reuptake inhibitors consisted of the largest proportion of reported ADRs [25]. The drug-wise distribution of reported ADRs actually shows prevailing institutional prescribing patterns rather than individual drug-specific risk as suggested by previous studies carried out by Sodhi *et al.* [15]. Polypharmacy is a very common problem in the different psychiatric prescriptions and this has been documented in a study conducted by Rahaman *et al.*, in a similar Eastern Indian tertiary-care hospital. This can increase the potential for drug-drug interactions and adverse effects [26].

Notably, clozapine, though associated with a less number of reactions, was linked with ADRs like agranulocytosis and sialorrhea, which are generally common due to it, as per the previous study conducted by De Las Cuevas *et al.* [19]. An additional 40 ADRs were attributed to the different other psychiatric drugs such as sertraline, paroxetine, aripiprazole, quetiapine, methylphenidate and pregabalin. Their ADRs included multiple organ systems, like gastrointestinal, neurological and dermatological systems, further increasing the need for personalized treatment. Few reported ADRs were associated with non-psychiatric drugs like brivaracetam, oxcarbazepine and ketamine, often prescribed concomitantly in psychiatric settings as reported previously by similar studies like those conducted by Zhao *et al.* and Lee *et al.* [20, 21]. After causality assessment, 63.3% of the ADRs came out to be probable, which is consistent, with a similar prospective tertiary care study conducted by Raju *et al.*, containing ADRs from different clinical departments in which probable ADRs constituted of 66% of the total number of ADRs [27]. But, other recent Eastern Indian studies have reported a predominance of possible causality [22, 23]. These differences reflect that there are some differences in the reporting patterns and the clinical information available for appropriate causality assessment. Taken together, the results show that there is a relevance of a few psychotropic drugs in contributing to ADRs. The findings also support the need for targeted pharmacovigilance and proper patient education. Special mention should be given to agents known for metabolic and neurological toxicity. Encouraging the reporting of ADRs can result in enhancement of patient safety and change in the different therapeutic consequences.

Conclusion:

We show the distribution of spontaneously reported ADRs in a tertiary care psychiatric setting, with central nervous system and metabolic reactions being most frequently documented. Although most ADRs were mild, and preventable events were identified. Strengthening pharmacovigilance practices, enhancing clinician awareness and improving systematic follow-up of reported ADRs may contribute to safer psychopharmacological management.

Limitations:

This study has several important limitations. First, the absence of exposure denominators (*i.e.*, total patients receiving each drug) prevents accurate estimation of incidence rates and comparative risk. Second, reliance on spontaneous reporting introduces underreporting and reporting bias, with more noticeable ADRs like sedation being overrepresented, while delayed or laboratory-detected reactions may be underreported. Therefore, the findings likely reflect reported events rather than the true burden of ADRs. Additionally, frequent polypharmacy complicates causality attribution to a single drug. Finally, as a single-centre study, the results may be influenced by local prescribing and reporting practices, limiting generalizability.

Advancement to knowledge:

This study provides contemporary real-world evidence on the pattern, causality, severity, preventability and outcomes of psychiatric adverse drug reactions in a tertiary care setting in Eastern India. The findings highlight the predominance of central nervous system and metabolic adverse reactions and identify commonly implicated psychotropic drugs. The assessment of preventability further emphasizes opportunities for improved monitoring and safer use of psychotropic medicines in routine clinical practice.

Declaration of competing interests: The authors have no competing interest to declare.

Acknowledgements: The authors have no acknowledgement to declare.

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